STATE OF MICHIGAN

DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS

OFFICE OF FINANCIAL AND INSURANCE REGULATION

Before the Commissioner of Financial and Insurance Regulation

In the matter of

XXXXX
Petitioner

v **File No. 121891-001-SF**

Blue Cross Blue Shield of Michigan
Respondent

_____

Issued and entered
this ____ day of November 2011
by R. Kevin Clinton
Commissioner

ORDER

I. PROCEDURAL BACKGROUND

On June 14, 2011, XXXXX, authorized representative of XXXXX(Petitioner), filed a request with the Commissioner of Financial and Insurance Regulation for an external review under Public Act No. 495 of 2006, MCL 550.1951 *et seq*. The Commissioner reviewed the material submitted and accepted the request on June 21, 2011.

The Petitioner is enrolled for health care benefits as an eligible dependent through the State of Michigan, a government self-funded health plan under Act 495. The plan is administered by Blue Cross Blue Shield of Michigan (BCBSM). Section 2(2) of Act 495, MCL 550.1952(2), authorizes the Commissioner to conduct this external review as though the Petitioner were a covered person under the Patient's Right to Independent Review Act, MCL 550.1901 *et seq.*

The Commissioner notified BCBSM of the external review request and asked for the information it used to make its final adverse determination. The Commissioner received BCBSM's response on June 30, 2011.

To address the medical issues in the case, the Commissioner assigned the matter to an independent medical review organization which provided its analysis and recommendation on July 5, 2011.

II. FACTUAL BACKGROUND

The Petitioner's prescription drug benefits are contained in BCBSM's *Preferred RX Program Certificate.*

The Petitioner was diagnosed with psoriatic arthritis and experiences joint weakness, swelling of joints, and severe knee pain. He requested authorization for the drug Humira.

BCBSM denied authorization for Humira, stating the Petitioner had not met its prior authorization requirements. The Petitioner appealed the denial through BCBSM's internal grievance process. At the conclusion of that process, BCBSM did not change its decision and issued a final adverse determination dated June 1, 2011.

III. ISSUE

Did BCBSM properly deny authorization for Humira?

IV. ANALYSIS

Petitioner's Argument

The Petitioner tried various medications, including over-the-counter pain relievers, hydrocodone, Darvocet, prednisone, and methotrexate. The Petitioner's rheumatologist believed that Humira therapy would provide significant clinical benefit and in a "To Whom It May Concern" letter dated June 2, 2011, wrote to BCBSM:

> [The Petitioner] has been diagnosed with psoriatic arthritis. He is currently on methotrexate. As you know, plaquenil can cause the psoriasis to worsen and sulfasalazine can interact with many of the medications he is on, including simvastatin. I advise you to approve Humira for the [Petitioner] as this is the best option for his arthritis.

The Petitioner argues that Humira is medically necessary and appropriate to treat his condition at this stage of his treatment because other medications are contraindicated. He believes Humira is a covered benefit under his certificate and that BCBSM is required to authorize and cover it.

BCBSM's Argument

It is BCBSM's position that Humira cannot be authorized because the Petitioner has not yet met the necessary criterion for coverage.

The Petitioner's group plan participates with BCBSM's pharmacy initiatives programs, and under that program prior authorization and step therapy is required when a brand name drug is prescribed and a generic form of the drug is available. A physician can request coverage for a brand name drug if generic alternatives have been tried and they have not worked or have produced significant side effects. For Humira, BCBSM requires a three-month trial with two concurrent disease modifying anti-rheumatic drugs (DMARDs), one of which must be methotrexate unless otherwise indicated.

The documentation BCBSM received indicated that the Petitioner has tried methotrexate, but has not tried a second DMARD, such as sulfasalzine, azathioprine, hydroxychlorquine/ chloroquine, cyclosporine, gold, or penicillamine.

Commissioner's Review

The Commissioner assigned this matter to an independent review organization (IRO) for analysis as required by Section 11(6) of the Patient's Right to Independent Review Act, MCL 550.1911(6). The IRO reviewer is a physician who has been in active practice for more than 12 years and is board certified in rheumatology. The IRO report contained the following analysis and conclusion:

> The MAXIMUS physician consultant noted that the member underwent a trial of methotrexate, which failed to control his disease. The MAXIMUS physician consultant also noted that the member's rheumatologist prescribed Humira for him, but that the Health Plan denied coverage for this medication on the grounds that the member had not failed a second disease modifying anti-rheumatic drug (DMARD) after methotrexate. The MAXIMUS physician consultant explained that Humira is both safer and more efficacious than any of the drugs on the Health Plan's list except methotrexate, which the member has already failed. The MAXIMUS physician consultant indicated that Plaquenil is relatively contraindicated because it is well known to be associated with flares of psoriasis. The MAXIMUS physician consultant also indicated that chloroquine would be expected to have a similar profile. The MAXIMUS physician consultant further indicated that cyclosporine and penicillamine have been largely abandoned in the contemporary practice of rheumatology due to unacceptable risks of toxicity and neither has been shown to be more efficacious than Humira in the treatment of psoriatic arthritis. The MAXIMUS physician consultant noted that gold has also fallen out of use and is not efficacious for the member's condition. [Citations omitted]
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> Pursuant to the information set forth above and available documentation, the MAXIMUS physician consultant determined that Humira is medically necessary for treatment of the member's condition.

While it is BCBSM's policy to require the failure of two DMARDS before approving coverage for a brand name drug, the IRO reviewer explained why a second three-month trial would not be reasonable in the Petitioner's case. The IRO reviewer concluded that Humira was medically necessary for the Petitioner at this time.

The Commissioner is not required in all instances to accept the IRO's recommendation, it is afforded deference. In a decision to uphold or reverse an adverse determination, the Commissioner must cite "the principle reason or reasons why the Commissioner did not follow the assigned independent review organization's recommendation." MCL 550.1911(16)(b). The IRO reviewer's analysis is based on extensive expertise and professional judgment and the Commissioner can discern no reason why that judgment should be rejected in the present case.

The Commissioner finds that BCBSM is required to authorize and cover the Petitioner's Humira prescription.

V. ORDER

Blue Cross Blue Shield of Michigan's final adverse determination of June 1, 2011, is reversed. BCBSM shall authorize and cover Humira within 60 days of the date of this Order, and shall, within seven (7) days of providing coverage, furnish the Commissioner with proof of compliance.

To enforce this Order, the Petitioner may report any complaint regarding implementation to the Office of Financial and Insurance Regulation, Health plans Division, toll free at (877) 999-6442.

This is a final decision of an administrative agency. Under MCL 550.1915, any person aggrieved by this Order may seek judicial review no later than 60 days from the date of this Order in the circuit court for the county where the covered person resides or the circuit court of Ingham County. A copy of the petition for judicial review should be sent to the Commissioner of Financial and Insurance Regulation, Health Plans Division, Post Office Box 30220, Lansing, MI 48909-7720.

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R. Kevin Clinton
Commissioner